Citation:

Cappuccio FP, Kerry SM, Micah FB, Plange-Rhule J, Eastwood JB. A community programme to reduce salt intake and blood pressure in Ghana [ISRCTN88789643]. A community programme to reduce salt intake and blood pressure in Ghana [ISRCTN88789643]. *BMC Public Health*. 2006 Jan 24; 6: 13. PMID: 16433927.

PubMed ID: 16433927

Study Design:

Cluster randomized trial

Class:

A - Click here for explanation of classification scheme.

Research Design and Implementation Rating:

POSITIVE: See Research Design and Implementation Criteria Checklist below.

Research Purpose:

To test the feasibility of salt reduction as a way of reducing blood pressure in villages in Ghana.

Inclusion Criteria:

Subjects aged 40 to 75 from rural and semi-urban villages were selected by stratified random sampling by age and sex from the census of all inhabitants in each village.

Exclusion Criteria:

No apparent exclusion criteria.

Description of Study Protocol:

Recruitment

Between June 2001 and June 2002 subjects aged 40 to 75 from each village were selected by stratified random sampling by age and gender from the census of all inhabitants in the village so that the total sample selected matched the overall population structure.

Design

Cluster randomized trial.

Dietary Intake/Dietary Assessment Methodology

The respondents were asked if they ate five salty foods (koobi, momoni, kako and all salted fish, salted pigs' feet and salted beef) regularly and whether they added salt at the table or during cooking.

Blinding Used

- Researchers sought to maintain blindness of the participants as to which dietary intervention they were receiving
- The community health nursing staff who taught about sodium restriction had to be aware of the main objectives of the study
- Assessment of blood and urine samples was presumably blinded.

Intervention

- An intensive health education program was carried out by community health workers with the sessions open to all villagers, irrespective of their participation into the trial
- The spirit of the intervention was to expose the whole community to the health promotion message and to test only a random proportion of them
- The public health issues included prevention of malaria, infective diarrheas and roundworm infection, as well as enhancing awareness of diabetes and high blood pressure. No mention was made of any possible dietary prevention of hypertension
- In the intervention villages additional advice was given not to add salt to food and in cooking, to limit the amount of koobi, momoni, kako and tilapia (salted fish), salted pigs' feet and salted beef and to soak the items in water overnight before eating them.

Statistical Analysis

- Blood pressure (BP) and pulse rate measurements were adjusted with a model that took into account time of day, age, gender, locality, body mass index (BMI) and interaction between age and gender prior to analysis
- The relationship between BP and sodium excretion, and between change in BP and change in sodium excretion were estimated using a random effects regression model with maximum likelihood estimation to allow for clustering within villages
- The intervention effect was estimated as the difference in the change in the outcome in the intervention and control groups so that a negative difference favors the intervention
- All analyses were carried out using Stata version 7.0.

Data Collection Summary:

Timing of Measurements

At baseline:

- A trained field worker completed a detailed questionnaire and measured height, weight and BP of each consenting participant
- Two consecutive timed 24-hour urine samples were obtained from each participant under close supervision.

Approximately one-hour educational sessions were held daily for the first week of the study and once weekly thereafter.

Participants were re-examined at three months and six months.

- At the three-month visit a history of drug therapy was taken, and weight, BP and pulse were measured and recorded
- Two 24-hour urine samples were collected but blood samples were not taken
- At six months the same measurements were made and a blood sample was taken as well.

Dependent Variables

- Variable 1: Change in 24-hour urinary sodium (UNa)
  - Two consecutive timed 24-hour urine samples were obtained from each participant under close supervision
  - The urine samples were transported the same day to Komfo Anokye Teaching Hospital. Aliquots were prepared and frozen at -20°C. Serum and urine were later shipped to London on dry ice for long-term storage
- Variable 2: Change in systolic blood pressure (SBP) (BP measured by a trained worker)
- Variable 3: Change in diastolic blood pressure (DBP).

Independent Variables

Dietary salt-lowering advice.

Control Variables

Included in adjusted statistical model:

- Age
- Sex
- Time of day
- Locality
- BMI
- Urinary potassium
- Urinary creatinine.

Description of Actual Data Sample:

- *Initial N:*
  - 2,743 subjects in 12 villages
  - 1,890 randomized to six intervention and six control villages
  - 1,013 attended baseline measurement
- *Attrition (final N):*
  - Intervention assessments at three months: 444; six months:399
  - Control assessments at three months: 450; six months:402
- *Age:* Adults 40-75 years
- *Ethnicity:* Ashanti region of central Ghana
- *Other relevant demographics:* Of the 1,013 participants in the study, 532 were from semi-urban and 481 from rural villages
- *Anthropometrics:*

	Intervention	Control
Age	54 (11)	55 (11)
Female N (percent)	324 (62)	304 (62)
BMI (kg/m^2)	21 (4)	21 (4)
SBP (mmHg)	129 (25)	127 (27)
DBP (mmHg)	77 (13)	76 (13)

Current smoking N (percent)	31 (6)	41 (8)
Alcohol drinking N (percent)	199 (38)	211 (43)
Hypertensive	154 (30)	137 (28)

Mean (SD)
Adapted from Table 2 of paper

- *Location:* The study was undertaken in 12 communities in the Ejisu-Juabeng and Kumasi Districts in the Ashanti region of central Ghana.

Summary of Results:

Adapted from Table 3. Baseline and three months or six months values for blood pressure (mmHg) and sodium and potassium excretion (mm per 24 hours) for participants followed up to each time-point.

Variable	**Baseline**		**Three Months**	
Baseline to month three	**Intervention (N=444)**	**Control (N=450)**	**Intervention (N=444)**	**Control (N=450)**
Systolic blood pressure	128.5 (24.7)	127.3 (26.3)	124.6 (26.6)	123.8 (26.0)
Diastolic blood pressure	76.8 13.0)	75.8 (13.5)	74.2 (13.7)	74.0 (14.1)
Urinary sodium	100.9 (44.3)	103.6 (45.3)	94.0 (44.5)	97.5 (42.3)
Urinary sodium: potassium	2.4 (1.2)	2.4 (1.3)	2.1 (1.1)	2.1 (1.1)
Urinary sodium: creatinine	12.4 (5.2)	12.8 (5.6)	12.4 (5.2)	13.0 (5.6)
	Baseline		**Six Months**	
Baseline to month six	**Intervention (N=399)**	**Control (N=402)**	**Intervention (N=399)**	**Control (N=402)**
Systolic blood pressure	129.2 (24.6)	125.6 (25.5)	127.9 (27.7)	127.4 (26.0)
Diastolic blood pressure	76.9 (13.0)	75.2 (13.3)	76.0 (14.2)	78.7 (14.3)
Urinary sodium	100.7 (45.2)	104.2 (45.5)	91.8 (41.8)	89.8 (39.1)
Urinary sodium: potassium	2.4 (1.3)	2.4 (1.3)	2.2 (1.2)	1.9 (1.0)
Urinary sodium: creatinine	12.4 (5.2)	12.8 (5.6)	11.9 (5.1)	11.7 (4.7)

Results are mean and SD.

Adapted from Table 4. Effect of intervention (control-intervention) on reduction in blood pressure (mmHg) and urinary sodium (UNa) excretion (mmol per 24 hour) at three and six months.

Variable	**Three Months (N=894)**	**Six Months (N=801)**
Systolic blood pressure	-0.48 (-5.45 to 4.50)	-2.54 (-6.54 to 1.45)
Diastolic blood pressure	-1.02 (-3.95 to 1.91)	-3.95 (-7.11 to -0.78)**

Urinary sodium	-0.5 (-12.3 to 11.3)	6.0 (-4.1 to 16.1)
Urinary sodium: creatinine	-0.01 (-1.35 to 1.32)	0.85 (-0.53 to 2.24)
Urinary sodium: potassium	0.08 (-0.22 to 0.39)	0.30 (0.02 to 0.57)*

Mean and 95% CI.

Values adjusted for age, sex, locality and BMI using random effect model.
Blood pressure adjusted for time of day.

*P=0.03; **P=0.015.

Other Findings

- The intervention and control groups were comparable for baseline characteristics
- Total salt consumed as measured by UNa was similar (99 vs. 103mmol per day) in rural villages and semi-urban settings
- Urinary K levels were higher in rural villages (58 vs. 40mmol per day; difference 18mmol per day [11 to 26]; P<0.001)
- In semi-urban vs. rural villages people were heavier (BMI 22.3 [4.6] vs. 19.8 [3.2]kg/m^2, P<0.001) and had higher BP (129/76 [26/14] vs. 121/72 [25/13]mmHg, P<0.001 for both SBP and DBP)
- The prevalence of HTN increased with age and was more common in semi-urban settings
- Effect of the intervention programme on salt intake.

Change in average sodium excretion

- Varied among villages
- It fell in four out of six villages in the intervention group and in five out of six villages in the control group
- The net intervention effect was a NS change in sodium excretion.

Relationship between urinary sodium and BP

- In all participants, regardless of intervention, there was a consistent relationship between the fall in UNa excretion and the fall in BP when adjusting for confounders
- There was a significant and positive relationship between the level of salt intake and both SBP and DBP
- After adjusting for potential confounding effects of age, gender, locality, BMI and clustering, there was a 2.2mmHg lower SBP and a 1.0mmHg lower DBP for a 50mmol per day lower urinary sodium excretion
- The relationships were significant also when expressed as Na-to-creatinine ratio and Na-to-K ratio.

Effect of the intervention programme on BP

- The intervention group showed a small reduction in both SBP and DBP, more pronounced at six months and statistically significant for DBP at six months using the adjusted model
- However, this effect was not consistent with observed UNa excretion since the Na excretion was lower in the control group at month six. (Intervention: 91.8mmol/L; Control: 89.8mmol/L).

Author Conclusion:

In West Africa the lower the salt intake, the lower the BP. It would appear that a reduction in the average salt intake in the whole community may lead to a small but significant reduction in population SBP.

Reviewer Comments:

- *The salt-lowering intervention was effective in the treatment group but the control group also had lower sodium excretion during the trial*
- *Irrespective of randomization, it was shown that a 2.2mmHg lower SBP and a 1.0mmHg lower DBP was associated with 50mmol per day lower UNa excretion when adjusted for confounders*
- *However, the results and conclusions drawn are difficult to interpret since **reduced BP** in the intervention group was associated with an **increase** in UNa excretion at month six. (Intervention: 91.8mmol/L; Control: 89.8mmol/L)*
- *These results may have limited use in other populations since the mean baseline DBP in both groups was already below recommended levels (77 intervention; 76 control) and the mean BMI (21) in both groups was low*
- *The population studied was rural African communities where the people are predominantly non-hypertensive and whose salt intake is lower than that found in most western countries.*

Strengths

- *Stratification at cluster level was done to avoid potential confounding due differences in localities*
- *Stratification was also done at individual level in order to achieve the same age-gender structure of the invited sample of each village*
- *The study provides estimates of BP and salt intake in the Ashanti region of Ghana.*

Limitations

- *The authors found changes in BP and sodium excretion within each intervention village were less than expected from the pilot study. They speculated that the control villages may have also received information about loweringNa, but were not sure how that occurred*
- *There is a possibility of confounding factors in BP measurement since time of day was controlled, but ambient temperature was not measured*
- *The study design aimed specifically at changing salt intake, without targeting other aspects of the participants' diet. It is conceivable that a combined approach with an increase in K intake and modification of fat intake might exert compounding effects on lowering of BP.*

Research Design and Implementation Criteria Checklist: Primary Research

Relevance Questions

1.	Would implementing the studied intervention or procedure (if found successful) result in improved outcomes for the patients/clients/population group? (Not Applicable for some epidemiological studies)	Yes

2.	Did the authors study an outcome (dependent variable) or topic that the patients/clients/population group would care about?	Yes
3.	Is the focus of the intervention or procedure (independent variable) or topic of study a common issue of concern to nutrition or dietetics practice?	Yes
4.	Is the intervention or procedure feasible? (NA for some epidemiological studies)	???

Validity Questions

1.	**Was the research question clearly stated?**	Yes
1.1.	Was (were) the specific intervention(s) or procedure(s) [independent variable(s)] identified?	Yes
1.2.	Was (were) the outcome(s) [dependent variable(s)] clearly indicated?	Yes
1.3.	Were the target population and setting specified?	Yes
2.	**Was the selection of study subjects/patients free from bias?**	Yes
2.1.	Were inclusion/exclusion criteria specified (e.g., risk, point in disease progression, diagnostic or prognosis criteria), and with sufficient detail and without omitting criteria critical to the study?	Yes
2.2.	Were criteria applied equally to all study groups?	Yes
2.3.	Were health, demographics, and other characteristics of subjects described?	Yes
2.4.	Were the subjects/patients a representative sample of the relevant population?	Yes
3.	**Were study groups comparable?**	Yes
3.1.	Was the method of assigning subjects/patients to groups described and unbiased? (Method of randomization identified if RCT)	Yes
3.2.	Were distribution of disease status, prognostic factors, and other factors (e.g., demographics) similar across study groups at baseline?	Yes
3.3.	Were concurrent controls used? (Concurrent preferred over historical controls.)	Yes
3.4.	If cohort study or cross-sectional study, were groups comparable on important confounding factors and/or were preexisting differences accounted for by using appropriate adjustments in statistical analysis?	N/A

3.5.	If case control or cross-sectional study, were potential confounding factors comparable for cases and controls? (If case series or trial with subjects serving as own control, this criterion is not applicable. Criterion may not be applicable in some cross-sectional studies.)	N/A
3.6.	If diagnostic test, was there an independent blind comparison with an appropriate reference standard (e.g., "gold standard")?	N/A
4.	**Was method of handling withdrawals described?**	Yes
4.1.	Were follow-up methods described and the same for all groups?	Yes
4.2.	Was the number, characteristics of withdrawals (i.e., dropouts, lost to follow up, attrition rate) and/or response rate (cross-sectional studies) described for each group? (Follow up goal for a strong study is 80%.)	Yes
4.3.	Were all enrolled subjects/patients (in the original sample) accounted for?	???
4.4.	Were reasons for withdrawals similar across groups?	Yes
4.5.	If diagnostic test, was decision to perform reference test not dependent on results of test under study?	N/A
5.	**Was blinding used to prevent introduction of bias?**	Yes
5.1.	In intervention study, were subjects, clinicians/practitioners, and investigators blinded to treatment group, as appropriate?	No
5.2.	Were data collectors blinded for outcomes assessment? (If outcome is measured using an objective test, such as a lab value, this criterion is assumed to be met.)	No
5.3.	In cohort study or cross-sectional study, were measurements of outcomes and risk factors blinded?	N/A
5.4.	In case control study, was case definition explicit and case ascertainment not influenced by exposure status?	N/A
5.5.	In diagnostic study, were test results blinded to patient history and other test results?	N/A
6.	**Were intervention/therapeutic regimens/exposure factor or procedure and any comparison(s) described in detail? Were interveningfactors described?**	Yes
6.1.	In RCT or other intervention trial, were protocols described for all regimens studied?	Yes
6.2.	In observational study, were interventions, study settings, and clinicians/provider described?	N/A
6.3.	Was the intensity and duration of the intervention or exposure factor sufficient to produce a meaningful effect?	Yes
6.4.	Was the amount of exposure and, if relevant, subject/patient compliance measured?	Yes

6.5.	Were co-interventions (e.g., ancillary treatments, other therapies) described?	N/A
6.6.	Were extra or unplanned treatments described?	N/A
6.7.	Was the information for 6.4, 6.5, and 6.6 assessed the same way for all groups?	Yes
6.8.	In diagnostic study, were details of test administration and replication sufficient?	N/A
7.	**Were outcomes clearly defined and the measurements valid and reliable?**	Yes
7.1.	Were primary and secondary endpoints described and relevant to the question?	Yes
7.2.	Were nutrition measures appropriate to question and outcomes of concern?	Yes
7.3.	Was the period of follow-up long enough for important outcome(s) to occur?	Yes
7.4.	Were the observations and measurements based on standard, valid, and reliable data collection instruments/tests/procedures?	Yes
7.5.	Was the measurement of effect at an appropriate level of precision?	Yes
7.6.	Were other factors accounted for (measured) that could affect outcomes?	Yes
7.7.	Were the measurements conducted consistently across groups?	Yes
8.	**Was the statistical analysis appropriate for the study design and type of outcome indicators?**	Yes
8.1.	Were statistical analyses adequately described and the results reported appropriately?	Yes
8.2.	Were correct statistical tests used and assumptions of test not violated?	Yes
8.3.	Were statistics reported with levels of significance and/or confidence intervals?	Yes
8.4.	Was "intent to treat" analysis of outcomes done (and as appropriate, was there an analysis of outcomes for those maximally exposed or a dose-response analysis)?	Yes
8.5.	Were adequate adjustments made for effects of confounding factors that might have affected the outcomes (e.g., multivariate analyses)?	Yes
8.6.	Was clinical significance as well as statistical significance reported?	Yes
8.7.	If negative findings, was a power calculation reported to address type 2 error?	Yes
9.	**Are conclusions supported by results with biases and limitations taken into consideration?**	Yes
9.1.	Is there a discussion of findings?	Yes

9.2.	Are biases and study limitations identified and discussed?	Yes
10.	**Is bias due to study's funding or sponsorship unlikely?**	Yes
10.1.	Were sources of funding and investigators' affiliations described?	Yes
10.2.	Was the study free from apparent conflict of interest?	Yes